REC'D 30 AUG 2005
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
501872 KXR		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NZ2004/000222	20 September 2004	18 September 2003

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] G01N 21/05, 33/577

Applicant

THE HORTICULTURE AND FOOD RESEARCH INSTITUTE OF NEW ZEALANDLIMITED

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      - [X] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

[X]	Box No. I	Basis of the report
[ ]	Box No. II	Priority
[ ]	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
[ ]	Box No. IV	Lack of unity of invention
[X]	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
[X]	Box No. VI	Certain documents cited
[ ]	Box No. VII	Certain defects in the international application
[X]	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
18 July 2005	16 August 2005
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**ROSS OSBORNE** Telephone No. (02) 6283 2404

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NZ2004/000222

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1-47, 52** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☒ the claims:

pages **48, 50,** as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **49, 51** received by this Authority on **18 July 2005** with the letter of 18 July 2005
pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/7-7/7** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/NZ2004/000222

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims		NO
Inventive step (IS)	Claims	1-18	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

D1 US6342349

D2 Wu Y. et al,

NOVELTY(N), INVENTIVE STEP (IS) Claims 1-18

D1 discloses an assay device that can be used with competitive binding assays that features 'dual linkers' with examples of a binding partner bound to a solid metal surface by means of a linker and in the liquid phase a binding partner bound through a linker to a optical signaller particle for the detection of analyte. D2 discloses the use of nanoparticles and linkers of optimized length to attach to binding partners for improved sensitivity in a flow through surface plasmon resonance-based immunoassay.

None of the prior art documents disclose an flow through immunoassay for the detection of haptens featuring an analyte/antibody bound through a linker to a high mass signalling molecule and a antibody/analyte bound to a sensor through a second linker. D2 does disclose the use of a signalling particle but the signal is an optical one. The claims are therefore novel.

The applicant's arguments that it would not be obvious to combine the teaching of D1 which is a non-flow through assay which may utilise multiple linkers with the teaching of D2 which is a flow through system that utilises only one linker are accepted. All claims therefore have an inventive step.

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/042403	21 May 2004	3 November 2003	4 November 2002

WO 2004/042403 discloses a plasmon resonance immunoassay which uses immunogold and a solid phase with attached substrate binding antibodies but does not disclose the use of dual linkers.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The claims are not concise, there are 6 independent claims among the 18 claims that define the invention. There does not appear to be six different substantively described variations of the invention in the description and these claims do not appear to differ in any fundamental manner. This lack of conciseness also leads to a lack of clarity about the precise ambit of the invention and matter should be addressed by reducing the number of independent claims.

The description only supports flow though assays where the signalling is done on the basis of mass, such as plasmon resonance assays and all the claims should be clearly limited to this type of assay. Otherwise some of the claims arguably cover dual linker assays such those described in D1 where there is a 'high mass' particle that signals on the basis of its optical properties and the options envisaged for the assays appear to include options where the sample flows through or over the detection sites.

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